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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,704	12/08/2003	Ravi P. Nargund	21151	3989

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,704	NARGUND ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4 and 49-66* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 54-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed December 22, 2006 is acknowledged. Original claims 1, 2 and 5-48 are canceled. New claims 49-66 are presented. Accordingly, claims 3, 4 and 49-66 are pending. It is noted claims 3 and 4 are dependent from a canceled claim. Cross-reference information to a related application is noted.

In the last Office Action Applicants elected the species for a pharmaceutical composition comprising 1) two appetite suppressants, 2) an appetite suppressant and a metabolic rate enhancer, 3) an appetite suppressant and a nutrient absorption inhibitor, 4) two metabolic rate enhancers, 5) a metabolic rate enhancer and a nutrient absorption enhancer, is acknowledged. Specifically, Applicants elected composition species, for 1) two appetite suppressants, AM 251 and phentermine; for 2) an appetite suppressant and a metabolic rate enhancer, AM 251 and L-796568; for 3) an appetite suppressant and a nutrient absorption inhibitor, AM 251 and orlistat; for 4) two metabolic rate enhancers, L-796568 and theophylline; for 5) a metabolic rate enhancer and a nutrient absorption inhibitor, L-796568 and orlistat.

Further, in response to the Restriction Requirement of record, Applicants elected methods and compositions comprising two active agents in the five categories *supra* in a method of treating obesity, that is unrelated to diabetes, overeating and bulimia.

Accordingly, newly submitted claims 54-66 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: The elected species under consideration were those set forth *supra* in compositions and methods of treating obesity. Treatment of diabetes was withdrawn from consideration in the last Office Action.

Since Applicants have received an Action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 54-66 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

The subject matter presently under consideration are specifically those appetite suppressant species recited *supra*, claims 49-53, drawn to compositions and methods of treatment of obesity of a non-diabetic etiology, comprising administering the compositions comprising the elected combination, AM251 and phentermine. Claims 3, 4, 54-66 and those combinations and methods of use not drawn to the treatment of obesity of a non-diabetic etiology, comprising AM251 and phentermine, are withdrawn from consideration by the Examiner, 37 CFR 1.42(b), as drawn to non-elected inventions. Re-affirmation of the elected subject matter is requested when Applicants respond to this Office Action.

Applicants' arguments set forth in the Amendment filed December 22, 2006 have been considered. However, rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejection is newly applied and constitutes the sole rejection being applied. In light of the new rejection, this Office Action is non-final.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al., U.S. Patent 5,597,797, and Hjorth et al., Society for Neuroscience Abstract Viewer and Itinerary Planner.

Clark teaches the co-administration of various appetite suppressants, such as phentermine, which may be combined with growth hormone and IGF-I, to treat or prevent obesity. See column 16, lines 26-65, as well as column 31, lines 55-57, where Clark teaches combination treatment results by far in the greatest loss of fat, suggesting a synergistic effect on fat loss. As required by instant claim 53, Clark teaches treatment of obesity-related disorders, such as polycystic ovarian disease or insulin resistance. See column 7, lines 56-67. Hjorth teaches the administration of the compound AM 251, 1-(2,4-dichlorophenyl)-5-(4-iodophenyl)-4-methyl-N-1-piperidinyl-1H-pyrazole-3-carboxamide, an inverse agonist at cannabinoid CB_1 receptors, results in weight loss.

Therefore, in view of the combined teachings of Clark and Hjorth, one skilled in the art would have been motivated to prepare and administer a composition comprising a combination of phentermine and AM 251 with a reasonable expectation of treating obesity. In the absence of a showing of unexpected results commensurate in scope with the claims, it would have been *prima facie* obvious to combine the agents to treat obesity. Both compounds are taught in the prior art to be useful in the induction of weight loss. In the absence of evidence to the contrary, it is *prima facie* obvious to use in combination two or more compounds that have previously been used separately for the same purpose. See *In re Kerkhoven*, 205 USPQ 1069. It is not inventive to

combine old ingredients of known properties. This is especially true in the field of obesity where combination therapies of known ingredients are conventional.

Specific statements in the references that would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involve not only what references expressly teach, but also what they would collectively suggest to one of ordinary skill in the art.

The open language of the present claims allows for the inclusion of any number of additional active agents.

No claim is allowed.

Zhou et al., Society for Neuroscience Abstract Viewer and Itinerary Planner, is cited to show further the state of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

March 24, 2007

Phyllis G. Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER